NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

AUXILIUM PHARMACEUTICALS, INC. & FCB I LLC,

Civil Action No.: 12-3084 (JLL)

Plaintiffs,

OPINION

v.

WATSON LABORATORIES, INC.,

Defendant.

LINARES, United States District Judge.

I. INTRODUCTION

This matter comes before the Court by way of multiple letters submitted by both Plaintiffs Auxilium Pharmaceuticals, Inc. and FCB I LLC (collectively "Plaintiffs") and Defendant Watson Laboratories, Inc. ("Watson") regarding the necessity for a claim construction hearing following Magistrate Judge Michael A. Hammer's denial of Watson's request to amend its invalidity contentions to add allegations of indefiniteness. Briefly, Plaintiffs argue that a claim construction hearing is not necessary while Defendant argues that the hearing is necessary. For the reasons set forth below, the Court finds that a claim construction hearing is unnecessary and therefore denies Defendant's request.

II. BACKGROUND

On March 8, 2013, the parties filed their Joint Claim Construction and Prehearing Statement. See ECF No. 54. In this submission, the parties disputed only three claim terms, all of which contain the word "viscosity" (the "viscosity terms"). Id. Plaintiffs contended that the

viscosity terms did not need construction as they could be understood in accordance with their plain and ordinary meaning. See Parties' Proposed Constructions and Evidence in Support Thereof, attached as Ex. A to Joint Claim Construction and Prehearing Statement, ECF No. 54. Watson's only argument as to its proposed construction was that the viscosity terms were indefinite and, therefore, had no plain and ordinary meaning. Id. at i ("There is an actual dispute over the meaning of these claim terms. Plaintiffs' proposed 'plain and ordinary meaning' construction does not address the problem that these terms are indefinite and have no 'plain and ordinary meaning.""). Importantly, on the date the parties filed the Joint Claim Construction and Prehearing Statement, Watson's Invalidity Contentions did not allege indefiniteness. Watson had, however, sought leave to amend its Invalidity Contentions to add allegations of indefiniteness and obviousness about a week before the Joint Claim Construction and Prehearing Statement was filed. See Watson's February 28, 2013 letter, ECF No. 50. On June 7, 2013, Judge Hammer granted Watson's motion to amend as to obviousness, but denied the motion as to Watson's request to argue indefiniteness. See Order, ECF No. 92. Shortly thereafter, Plaintiffs filed a letter asserting claim construction had become unnecessary because Watson's sole argument in the Joint Claim and Prehearing Statement was that the viscosity terms are indefinite. See Plaintiffs' June 14, 2013 letter, ECF No. 96.

In response, Watson stated that claim construction remained necessary and Judge Hammer's Order did not prohibit Watson from asserting, during claim construction, that the viscosity terms are indefinite. See ECF No. 100. Watson's argument was partially premised upon footnote 7 of Judge Hammer's June 7, 2013 Opinion:

The parties also argue whether Watson should be allowed to make an indefiniteness argument as part of its claim construction briefing irrespective of what is contained in its invalidity contentions. The Federal Circuit has recently explained that "indefiniteness is a question of law and in effect part of claim construction." <u>ePlus, Inc. v. Lawson Software, Inc.</u>, 700 F.3d 509, 517 (Fed. Cir. 2012). Nevertheless, the issue of what arguments Watson can or cannot make at claim construction is not before the Court today and it need not decide that issue.

Opinion, ECF No. 92, at 15 n.7. Watson further argued that indefiniteness remains crucial to the issue of noninfringement and the Federal Circuit has made clear that indefiniteness is to be resolved during claim construction. See Watson's June 17, 2013 letter, ECF No. 100, at 2.

Shortly thereafter, Plaintiffs notified the Court that, to "streamline this case and in the interest of judicial economy," Plaintiffs would pursue only claims for which infringement was not disputed. See Plaintiff's July 25, 2013 letter, ECF No. 111, at 1. That shift in Plaintiffs' position appeared to moot Watson's argument that claim construction remained necessary to determine infringement. Id. at 1-2.

Watson responded by asserting that the viscosity terms still needed to be construed because Watson still had invalidity defenses, such as obviousness and improper inventorship, to all of the remaining claims. See Watson's July 29, 2013 letter, ECF No. 112. Watson averred that claim construction still had to occur because claims must be construed before the court can make a validity determination. Id.

In response, Plaintiffs asserted that Watson's arguments continue to change. Plaintiffs categorized Watson's positions as follows: (1) prior to a decision on its motion to amend, Watson argued that claim construction was only necessary to determine indefiniteness; (2) after Watson's motion to amend was denied, Watson then argued claim construction was necessary to determine infringement; (3) after Plaintiffs removed infringement from the case, Watson next argued claim construction was necessary for other invalidity defenses. See Plaintiffs' August 1, 2013 letter, ECF No. 115. Plaintiffs argued that Watson's Amended Invalidity Contentions,

however, "contain no discussion whatsoever of how the construction of the 'viscosity' terms has any bearing on those defenses." <u>Id.</u>

The need for claim construction was addressed during the November 19, 2013 hearing before Judge Hammer. See Hr'g Tr., ECF No. 136. While the parties' arguments largely mirrored their letters, Plaintiffs also posited that Watson's experts' ability to interpret the viscosity determines contradicted Watson's assertion that the terms were indefinite. Id. at 6:11-19.

On March 17, 2014, Watson again wrote to the Court on this issue. <u>See</u> Watson's March 17, 2014 letter, ECF No. 157. In that letter, Watson summarized the then-pending disputes in this case, which included "whether claim construction is required in this case, so that Watson may raise issues of indefiniteness[.]" <u>Id.</u> at 1.

Judge Hammer held a hearing on April 1, 2014, during which His Honor heard additional argument on this issue. Again, the parties' arguments largely mirrored their submissions, but several new arguments were advanced. Plaintiffs note that the standards for claim construction and a determination of invalidity due to indefiniteness are different and Watson's argument that the viscosity terms are indefinite would convert the Markman hearing into a motion for summary judgment. See April 1, 2014 Hr'g Tr., at 8:17-9:14. Furthermore, Plaintiffs contend that Watson's expert reports addressing other invalidity defenses, such as obviousness, do not raise the viscosity issue. Id. at 10:1-11.

When asked by Judge Hammer, Watson confirmed that, by advancing indefiniteness at claim construction, Watson was, in effect, seeking a determination that the patents were invalid. <u>Id.</u> at 16:21-17:5.

III. ANALYSIS

The Court begins its inquiry with the Local Patent Rules. Local Patent Rule 3.3 requires a party opposing an assertion of patent infringement to serve upon all other parties its "Invalidity Contentions." Subsection (d) requires that these Invalidity Contentions must include "[a]ny grounds for invalidity based upon 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims." A patent is indefinite if it is "not amenable to construction' or 'insolubly ambiguous." <u>Datamize</u>, <u>LLC v. Plumtree Software, Inc.</u>, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (quoting <u>Novo Indus.</u>, <u>L.P. v. Micro Molds Corp.</u>, 350 F.3d 1348, 1353 (Fed. Cir. 2003); <u>Honeywell Int'l, Inc. v. Int'l Trade Comm'n</u>, 341 F.3d 1332, 1338 (Fed. Cir. 2003); <u>Exxon Research & Eng'g Co. v. United States</u>, 265 F.3d 1371, 1375 (Fed. Cir. 2001)). The idea behind indefiniteness is simple: A patent is supposed to demarcate to a person of skill in the art the bounds between what is claimed and what is not. <u>See United Carbon Co. v. Binney & Smith Co.</u>, 317 U.S. 228, 236 (1942). If a person of requisite skill is unable to make that determination, then the patent is invalid.

As noted above, Judge Hammer denied Watson's motion to amend its Invalidity

Contentions to include an assertion of indefiniteness. Therefore, the question before the Court is
whether a party that does not assert indefiniteness in its invalidity contentions, as required by

Local Patent Rule 3.3(d), nonetheless can argue during claim construction that certain claim
terms are indefinite and, therefore, the patents-at-issue are invalid.

Prior to answering this question, the Court notes that several other related questions are not raised in the instant dispute.

First, the Court need not consider whether claim construction is necessary as to claim terms for which infringement is disputed, as Plaintiffs notified the Court that they now advance

only claims for which Watson does not contest infringement. <u>See</u> Plaintiffs' July 25, 2013 letter, ECF No. 111.

Second, the Court is not addressing whether Watson's failure to raise indefiniteness in its Invalidity Contentions precludes it from raising at claim construction an argument that is relatedto-but-distinct-from indefiniteness. Here, as Watson recognized during the hearing before Judge Hammer, Watson's sole argument in its proposed construction of the viscosity terms is that the claim terms are indefinite and, therefore, the patents-at-issue are invalid. April 1, 2014 Hr'g Tr. At 16:21-17:5. In its motion to amend, Watson sought leave to argue that the viscosity terms were invalid as indefinite under 35 U.S.C. § 112 ¶ 2 because those terms are not amenable to construction because a "person of ordinary skill in the art . . . would be unable to ascertain the conditions under which the viscosity of a potentially infringing pharmaceutical composition should be measured." See Proposed Amended Invalidity Contentions, ECF No. 50-1, at 36. Watson now seeks to argue, during claim construction, that these terms are indefinite because the claims do not set forth "any apparatus or any testing conditions and parameters for the claimed viscosity testing." See Parties' Proposed Constructions and Evidence Support Thereof, ECF No. 54. These arguments are functionally identical and seek the same result: a determination of invalidity based upon the indefiniteness of the viscosity terms.

Third, the Court is not addressing what constitutes sufficient compliance with Local Patent Rule 3.3(d). There is no dispute that indefiniteness is completely absent from Watson's Amended Invalidity Contentions.

Fourth, the issue before the Court is not whether "indefiniteness is a question of law and in effect part of claim construction." See ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 517 (Fed. Cir. 2012). The Federal Circuit has clearly answered that question in the affirmative.

<u>Id.</u> Instead, the issue before the Court is whether a party that does not assert indefiniteness in its invalidity contentions, as required by Local Patent Rule 3.3(d), nonetheless can argue during claim construction that certain claim terms are indefinite and, therefore, the patents-at-issue are invalid.

In answering that question, the Court first examines the purpose of the Local Patent Rules. The District of New Jersey promulgated the Local Patent Rules in 2009 for the administration of "all civil actions . . . which allege infringement of a patent." L. Pat. R. 1.2. Those rules require early disclosure of the patentee's infringement contentions and the alleged infringer's invalidity contentions. Sanofi-Aventis v. Barr Labs., Inc., 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (describing the disclosure requirements as "ultra early" (emphasis in original)). The purpose of such early disclosure is "to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." King Pharm., Inc. v. Sandoz Inc., Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting Computer Accelerations Corp. v. Microsoft Corp., 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)) (internal quotation marks omitted). The rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." King Pharm., 2010 WL 2015258, at *4 (citing Atmel Corp. v. Info. Storage Devices, Inc., Civ. No. 95-1987, 1998 U.S. Dist. LEXIS 17564, at *2 (N.D. Cal. Nov. 5, 1998)) (internal quotation marks omitted)).

"Local Patent Rule 3.3 governs the service of a party's infringement contentions and is very specific with regard to what must be included in the disclosure[.]" Merck Sharp & Dohme Corp. v. Sandoz, No. 12-3289, at *2 (D.N.J. Jan. 6, 2014). As noted above, Rule 3.3(d) requires a party to set forth the "grounds of invalidity based on . . . indefiniteness[.]"

While the substance of this case may be complicated, the issue before the Court is quite simple. Rule 3.3(d) required Watson, if it wanted to argue the patents were invalid for indefiniteness, to set forth the grounds for this argument in its invalidity contentions. In fact, Watson did attempt to bring indefiniteness into the case through its motion to amend. That motion, however, was denied. If the Court were to accept Watson's argument that it can argue the viscosity terms are indefinite, and therefore the patents-at-issue are invalid, during claim construction (or at trial) even though Watson failed to comply with Rule 3.3(d), Rule 3.3(d) would be rendered meaningless. The Court declines to write subsection (d) out of Local Patent Rule 3.3.

A comparison to the Federal Rules of Civil Procedure is illustrative. Federal Rule of Civil Procedure 8 requires parties to set forth their claims for relief and/or defenses to claims in their pleadings. If a party wishes to later add a claim or defense, Rule 15 requires the party to amend its pleading. Putting aside the fact that the standard for amendment pursuant to Rule 15 is less onerous than the standard for amendment pursuant to Local Patent Rule 3.7, even Rule 15 does not allow a party to advance a claim or defense without amendment. Similarly, Federal Rule of Civil Procedure 12(h) provides that a litigant waives certain defenses, such as insufficient process, if that litigant fails to raise that defense by motion or it its responsive pleading. If a court were to allow a litigant to first assert this defense in the context of a motion for summary judgment following the completion of fact and expert discovery, the court would effectively render the "use it or lose it" provision of Rule 12 meaningless.

Here, because Watson did not raise an indefiniteness defense in its invalidity contentions, the Court concludes Watson cannot now seek a determination that the patents-at-issue are invalid for indefiniteness through claim construction.

This conclusion, however, does not end the Court's inquiry. The Court must next consider whether claim construction is necessary under these unique circumstances.

Specifically, in the Joint Claim Construction and Prehearing Statement, Plaintiffs assert no claim construction is necessary because "viscosity" can be assigned an ordinary and plain meaning and Watson argues construction is impossible because the terms are indefinite. See Joint Claim Construction and Prehearing Statement, ECF No. 54. As noted above, however, Watson is precluded from making this argument. Therefore, the Court is, in effect, left without any proposed construction for these terms other than Plaintiffs' assertion that the viscosity terms can be accorded their plain and ordinary meaning.

"Trial courts have broad powers of case management, including over the process of claim construction." Mars, Inc. v. JCM Am. Corp., Civ. No. 05-3165, 2008 WL 2684118, at *13 (D.N.J. July 2, 2008) (citing Jack Guttman. Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002). A court may determine construction of a claim term is unnecessary in many circumstances. As the parties recognize, "[w]here the parties have agreed that terms do not require construction, the plain and ordinary meaning of the claim terms govern." Joint Claim Construction and Prehearing Statement, ECF No. 54, at 3. Similarly, claim construction may be unnecessary when a term's construction is undisputed. See Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356, 1366–67 (Fed. Cir. 2004) (citing U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1567 (Fed. Cir. 1997)); see also Netscape Comm'ns Corp. v. ValueClick, Inc., 684 F. Supp. 2d 678, 684 n.9 (E.D. Va. 2009) (noting it was unnecessary to construe a term when it was undisputed); Pavilion Techs., Inc. v. Emerson Elec. Co., No. 05-898, 2006 WL 6210180, at *12 (W.D. Tex. Sept. 5, 2006) (noting it was unnecessary to review a special master's recommended constructions when no party objected to those constructions). Moreover, a court may decline to

construction on those claims fails to explain why construction of the claim terms is necessary.

Mars, 2008 WL 2684118, at *13.

In O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd., the Federal Circuit held that a trial court's refusal to construe the term "only if" was legal error because, even though the parties agreed that the term had an ordinary and plain meaning, the parties disputed what circumstances satisfied the requirement specified by the claim term. 521 F.3d 1351, 1361-62 (Fed. Cir. 2008). In that case, however, the trial court was presented with two concrete but contradictory interpretations of this term. <u>Id.</u> Here, Watson's sole proposed claim construction argument is that the viscosity terms are indefinite and the Court has concluded this argument is barred by Local Patent Rule 3.3(d). In effect, Watson has not offered the Court a contrary construction and, therefore, the Court has not been presented with a genuine and legitimate dispute that it must resolve. See id. at 1362 ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); see also U.S. Surgical, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings[.]"); Am. Piledriving Equip., Inc. v. Geoquip, Inc., 637 F.3d 1324, 1331-32 (Fed. Cir. 2011) (recognizing that the existence of a dispute on infringement or invalidity does not mean that claim construction is necessary); Perfect Web Techs. v. InfoUSA Inc., 587 F.3d 1324, 1332 (Fed. Cir. 2009) ("[A] district court need not construe undisputed claim terms prior to issuing a summary judgment of invalidity.").

There are several other case-specific considerations that suggest claim construction proceedings are unnecessary. First, this matter is proceeding as a bench trial before this Court. If the Court concludes at trial that the record is insufficient to reach a final determination in this

case, nothing in this decision prohibits this Court from taking whatever actions necessary to

adjudicate the case's merits. As the parties noted at the hearing before Judge Hammer, claim

construction can occur at any time, even at trial. See April 1, 2014 Hr'g Tr., at 53:12-54:9.

Second, it is unclear from the record how a claim construction hearing would assist the Court or

the parties as the only argument Watson could make is that the terms are indefinite, which

Watson is precluded from arguing. See id. at 16:21-17:5. Third, the only claims that Plaintiffs

are advancing are claims for which infringement is not contested and, while Watson has raised

invalidity defenses to these uncontested-infringement claims, Watson has not explained how the

viscosity terms relate to these defenses. For example, Watson does not explain how construction

of the viscosity terms is necessary to determine whether the patents-at-issue failed to name the

proper co-inventors.

Based upon the foregoing, the Court concludes that claim construction proceedings are

not necessary. An appropriate order accompanies this Opinion.

Inited States District Judge

Dated: June II, 2014

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